

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/567,073	Applicant(s) BRYAN, PHILIP N.
Examiner WILLIAM W. MOORE	Art Unit 1656

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 February 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____
Claim(s) objected to: 9 and 10
Claim(s) rejected: 1-8, 11-17 and 46-49
Claim(s) withdrawn from consideration: 18-45 and 50-61

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). 20081013.
13. ☒ Other: Note attached PTO-892, Notice of References cited.

/Rebecca E. Prouty/
Primary Examiner, Art Unit 1652

Continuation of 3. NOTE: New claim 62 is added, but no claims were cancelled.

Continuation of 11. does NOT place the application in condition for allowance because:

(d) The claims may not be entered unless and until they comply with 37 CFR 1.116. Amendments of 27 February 2009 to claims 1, 3, 4, 5-8, 10, 13-15, 18, 21, 46, 48, and 49 are considered to advance prosecution where they overcome the objection of record for lack of Sequence Rules compliance.

(a) The claims submitted 27 February 2009 raise new issues because, were a claim cancelled to permit consideration of claim 62, that claim would require further search of the prior art to identify the particular affinity required among the broad range indicated at page 18 of the specification. The new claim 62 would also raises new issues under the first paragraph of 35 USC 112 where no particular structure that affords a particular dissociation constant, currently inappropriately expressed in the claims as "binding affinity", is indicated in claim 1 from which claim 62 depends.

(c) While the amendments of 27 February 2009 clarify the intended subject matter, they are not deemed to materially reduce or simplify issues for appeal because, with regard to Applicant's arguments submitted 27 February 2009:

1) The amendatory introductions of "protease" and "protein" in claims 3, 7, and 13 does not remove these claims from the rejection of record under the second paragraph of 35 USC 112. The phrase "variant thereof" remains indefinite without the identification a particular structure with which comparison can be made. Appendix B only establishes that a genus of serine proteases may be considered subtilisins. Which is a variant and which is not a variant?

2) Van Rooijen disclose the use of a "chymosin propeptide", and chymosin is a serine protease, thus the claim amendments cannot displace the anticipatory disclosure of Van Rooijen et al. as applied to the claims 1, 46, and 47 under 35 USC 102(e). The "presently-claimed constructs of claims 1, 46 and 47" require no particular structures for fusion polypeptides encoded by a polynucleotide, only that an amorphous "prodomain" be linked, without any indication of orientation, to a fusion partner of interest.

3) Applicant argues limitations absent from the claims previously examined in traversing the rejection of record under 35 USC 103(a). The broadest range of "high" affinity at page 18 of the specification is "nM to pM". Rather than presenting a new claim 62, Applicant may consider amending a claim already under examination by introducing the specific limitation, "10nM", found at lines 23-24 of page 18 of the specification, lest new matter be introduced", or amending a claim already under examination by introducing one of the other two, specific, dissociation constants, "10pM" and "<100pM" found at line 24 of page 18 of the specification. Note however, that such amendment(s) introducing such functional limitations may implicate issues of written description and enablement of the already quite generic subject matters of the claims now subject to rejections over the prior art.